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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,944	12/22/1999	Gerard Gundling	6653.US.01	6792

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
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1637

260

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/470,944

Applicant(s)

GUNDLING, GERARD

Examiner

Alexander H. Spiegler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-10 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

1. This action is in response to Applicant's response, filed on January 22, 2004. Currently, claims 1-2, 4-10 and 12-16 are pending. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2 and 4-10 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uematsu et al. (EP 0757106 A2, 1997), in view of Kim et al. (WO 92/18514), and further in view of Chomczynski (USPN 5,945,515).

Uematsu et al.

Uematsu et al. disclose a method for isolating a nucleic acid by mixing a metal oxide support, a material containing a nucleic acid, and a solution for extracting the nucleic acid forming a sample solution, separating the metal oxide support to which the nucleic acid has been bonded from the sample solution, and eluting the nucleic acid from the magnetic carrier to which the nucleic acid has been bonded (pg. 3, ln. 42-45). Uematsu et al. further teach that the solution

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used in the extraction of the nucleic acid contains a buffer containing a chaotropic material, such as guanidine salts, potassium iodide, sodium thiocyanate, sodium isothiocyanate, and urea (pg. 5, ln. 54-56). Furthermore, the reference teaches that the buffer can be used in combination with Triton X-100, a known detergent, and Tris HCl buffer (pg. 5, ln.56 - pg.6 ln. 1). With respect to claim 5, the reference further teaches a wash step of an aqueous solution of about 70% ethanol, following the separation of the metal oxide support/nucleic acid complex from the sample solution (pg.5, 43-44). With respect to claim 6, Uematsu et al. teach that following the wash step the nucleic acid is then eluted from the metal oxide support, with a Tris-EDTA buffer (TE buffer), or sterilized water (pg. 5, ln. 45). With respect to claim 7, the reference further teaches the detection of the nucleic acid after eluting the nucleic acid from the metal oxide support (pg. 3, ln. 57 - pg. 4, ln. 6). With respect to claim 8, the reference further teaches the step of amplifying the eluted nucleic acid (pg. 4, ln. 8-9). With respect to claim 9 and 10, the reference teaches that the nucleic acid used is RNA or DNA, and is taken from a biological source (i.e. whole blood, urine) (pg. 2-3).

Uematsu et al. teach a kit for isolating nucleic acid comprising a metal oxide support and a solution for extracting the nucleic acid, which is composed of a chaotropic agent, a detergent, and an elution buffer comprising water (pg. 4, ln. 10-12).

With respect to claim 12, the reference teaches (pg. 14, ln. 34-35) the amplification of the nucleic acid without the removal of the elution buffer.

With respect to claims 13-14, Uematsu teaches the elution of the nucleic acid can be conducted in a solution having a low ionic strength (for example, sterilized water, which has a pH of 7.0) (pg. 6, ln. 8-9).

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Uematsu fails to teach:

- 1) Immobilizing the nucleic acid by forming a bond between the nucleic acid and the metal oxide support.
- 2) A binding buffer further comprising an organic solvent, wherein the flashpoint of the binding buffer is greater than 130 degrees Fahrenheit or the use of a reducing agent.

Kim et al.

Kim teaches the purification of nucleic acids using metal oxide supports. Specifically, the reference teaches the bonding of nucleic acid directly to a metal oxide support material (pg. 7, ln. 11-25), which provides the advantage in that the bonded nucleic acids can be readily isolated (pg. 3, ln. 14-21), and provides the benefits of an optimal combination of such properties as recovery, relative purity, and biological activity of the recovered nucleic acid, as well as, versatility, cost, speed, simplicity, and ease of use (pg. 3, ln. 31-35).

The reference also teaches that any biological sample containing the desired nucleic acids (pg. 3, ln. 22-30). With respect to claims 15-16, Kim teaches the elution of a bound nucleic acid from a metal oxide support material using potassium phosphate (Example 5, pgs. 17-18). In particular, Kim teaches that 30mM potassium phosphate is effective to recover 86% of bound DNA (pg. 17).

Chomczynski

Chomczynski teaches a solution for isolation of RNA, DNA, and proteins from biological material, where the solution comprises a chaotropic agent, detergent, and organic solvent (col. 10, ln. 22-34). With respect to claim 3, Chomczynski teaches that the addition of substantially lower amounts of organic solvents are required to effect the precipitation of cellular components (col. 3, ln.65-68). With respect to claims 2 and 4, Chomczynski further teaches that the solution for the isolation of RNA, DNA, and proteins, also comprises a reducing agent (see abstract, and col. 4 ln. 4). Chomczynski teaches that the reducing agent facilitates denaturation of RNase by the chaotropes and aids in the isolation of undegraded RNA.

With respect to claims 1-2 and 4-10, 12-14:

In view of the teachings of Kim, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Uematsu so as to have performed the method of separating nucleic acids from a test sample through the bonding of the nucleic acid to a metal oxide support material, in order to have achieved the benefits stated by Kim of providing a more versatile, cost-effective, and more efficient means of separation.

In view of the teachings of Chomczynski, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Uematsu and Kim so as to have added an organic solvent to the binding buffer, in order to have achieved the benefit of effecting the precipitation of cellular components (which would be expected to have a flashpoint of greater than 130⁰ F); and a reducing agent to the binding buffer in order to have achieved the advantages stated by Chomczynski of enhancing the denaturation of RNase present in the sample, thereby improving the isolation of RNA from the sample.

With respect to claims 15-16, in view of the teachings of Kim, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods of Uematsu et al. so as to have used an elution buffer which comprises potassium phosphate in place of TE buffer in order to have provided an equally effective means for eluting the nucleic acids and providing a suitable medium for storing the eluted nucleic acid.

Applicants Arguments

Applicant argues Kim fails to support the prima facie obviousness rejection. Specifically, Applicant argues the cited portions of Kim do not “provide a complete recipe for practicing the claimed invention”, and that this is not “surprising” because the Kim reference is a patent application wherein “the ordinarily skilled artisan would recognize, the function of the claim in a patent application is to define the metes and bounds of what the patent applicant claims as his own.” (See Applicant’s remarks). Accordingly, Applicant argues the cited portions of Kim cannot “reasonably suggest to the ordinarily skilled artisan that no purification or precipitation step need be performed”. (See Applicant’s remarks).

Applicant also argues Kim’s teaching that any biological sample can be used as a test sample is “routine in patent applications”, and that this “operates as a shield against interpretations that the nucleic acids can only be purified from those sources described in the working examples.” (See Applicant’s remarks).

Applicant argues Kim must be read in view of the common knowledge of those skilled in the art. Applicant then cites a 1982 reference and states, “the ordinarily skilled artisan, at the

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time Kim was filed understood how to perform multiple purification steps to partially purify nucleic acids from complex materials.” (See Applicant’s remarks). Applicant additionally states, “the ordinarily skilled artisan would recognize that Kim binds purified nucleic acids directly to the metal oxides, or when the nucleic acid is not purified, discloses the use of additional methods to partially purify the nucleic acid before binding the nucleic acid to the metal oxide.” (See Applicant’s remarks).

Applicant also points to one of Kim’s preferred embodiments and argues that this embodiment is different than the claimed invention.

Response to Applicants Arguments

Applicant's arguments have been fully considered but they are not persuasive for the following reasons:

First, while Kim teaches examples of precipitation and purification of nucleic acids prior to binding to the metal oxide support, the cited portions of Kim teach that this is not an absolute requirement of his invention. Specifically, the cited portions of Kim clearly teach that the binding of nucleic acids that have not been purified or precipitated are encompassed in his invention. Applicant’s assertion that the cited portions of Kim do not “provide a complete recipe for practicing the claimed invention”, and that this is not “surprising” because the Kim reference is a patent application is not based on fact. This assertion appears to be based on opinion, is without foundation, and is not supported by the record. Applicant’s statement that “the ordinarily skilled artisan would recognize, the function of the claim in a patent application is to define the metes and bounds of what the patent applicant claims as his own” supports the notion

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that Kim did not intend to limit his invention as Applicant argues, and therefore, Kim claims the binding of nucleic acids that have not been purified or precipitated as his own. Furthermore, Applicant's argument that the cited portions of Kim cannot "reasonably suggest to the ordinarily skilled artisan that no purification or precipitation step need be performed" is merely speculative, especially in light of Kim's explicit teaching that the binding of nucleic acids that have not been purified or precipitated are encompassed in his invention.

Second, Applicant's assertion that Kim's teaching that any biological sample can be used as a test sample is "routine in patent applications", and that this "operates as a shield against interpretations that the nucleic acids can only be purified from those sources described in the working examples" is not persuasive. This argument is speculative, and is not supported by the record. Furthermore, Applicant has not provided any evidence to contradict Kim's assertions that any biological sample containing the desired nucleic acid can be a test sample.

Third, Applicant's argument with respect to common knowledge of those skilled in the art at the time of the Kim is not persuasive. First, Applicant's reliance on a 1982 teaching provides, at best, only what was common knowledge in 1982, and not what may have been common knowledge in 1991 when Kim filed his Application. Furthermore, Applicant's assertions as to what the ordinarily skilled artisan would recognize from Kim's teaching also appears to be in the form of an opinion, and is not supported by fact or the record. For example, Applicant has not provided a declaration or relevant art contrary to the explicit teachings of Kim.

Finally, Applicant's assertion that one of Kim's preferred embodiments is different than the claimed invention is also not persuasive. The fact that one of Kim's preferred embodiments does not teach all of the limitations of the claimed invention only mitigates against using this

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preferred embodiment and this reference as an anticipatory reference. However, this rejection is a 103 rejection, and not a 102 rejection.

Conclusion

4. No claims are allowable.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

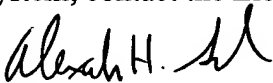
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (571) 272-0747. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Alexander H. Spiegler
May 11, 2004


CARLA J. MYERS
PRIMARY EXAMINER